Charles Darwin University

Final Examination

Family Name						
Given Name/s						
Student Number						
Teaching Period	Semester 2, 2017					

PHA306 – Advanced Pharmaceutics	DURATION	
	Reading Time:	10 minutes
	Writing Time:	120 minutes

INSTRUCTIONS TO CANDIDATES

The exam consists of 4 Sections (A, B, C & D). All sections need to be answered in the 20-page booklet provided
Section A (1-8): 31 marks
Section B (1-7): 24 marks
Section C (1-8): 31 marks
Section D (1-6): 19 marks
Total marks of the exam: 105 marks

EXAM CONDITIONS

You may begin writing from the commencement of the examination session. The reading time indicated above is provided as a guide only.

This is a CLOSED BOOK examination

Any non-programmable calculator is permitted

No handwritten notes are permitted

No dictionaries are permitted

ADDITIONAL AUTHORISED MATERIALS	EXAMINATION MATERIALS TO BE SUPPLIED
No additional printed material is permitted	1 x 20 Page Book

THIS EXAMINATION IS PRINTED DOUBLE-SIDED.

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Section A (31 marks)

1. Heat sterilization is one of the common methods of sterilization. What are the factors that can increase the efficiency of heat inactivation?

(4 marks)

2. The time required to inactivate a specific load (bioburden) of *Escherichia coli* (*E. coli*) at 110 ^{o}C is 20 minutes. Q_{10} for *E. coli* is 2.
   I. Define Q_{10}.

(2 marks)

   II. What is the time required to inactivate the same load of *E. coli* at 120 ^{o}C?

(2 marks)

3. What is the difference between "Decimal reduction time D-value" and "Thermal death time"?

(3 marks)

4. Sterilization method A has an $F_0 = 20$
   Sterilization method B has an $F_0 = 30$
   I. What is F_0?

(2marks)

   II. Which method is considered more effective method of sterilization?

(2 marks)

5. Organic contaminants can reduce the effectiveness of some disinfectants. What are the mechanisms involved in reducing the disinfectant's effectiveness by organic contaminants?

(4 marks)

6. What are the advantages of moist-heat sterilization?

(4 marks)

7. Compare between the following sterilization methods in relation to the mechanism of M.O inactivation.

(4 marks)

Moist heat	Dry heat	Irradiation	Chemical	Filtration

8. Mention FOUR characteristics of membrane filters.

(4 marks)

End of Section A

Section B (24 marks)

1. Mention TWO advantages and TWO disadvantages to intramuscular route of administration.

(4 marks)

2. What is the meaning of "compatible via Y-site" based on the "Australian injectable drugs handbook"?

(2 marks)

3. Explain the following incompatibilities:

   I. Diluting diazepam injection beyond four-folds produces white precipitate.

(2 marks)

   II. Adding phenytoin injection to dextrose 5% infusion bag will cause immediate precipitation of phenytoin.

(2 marks)

4. A pharmacist receives a medication order for 300,000 units of penicillin G potassium to be added to 500 mL of D5W (Dextrose 5% in Water). The directions on the 1,000,000-unit package state that if 1.6 ml of solvent are added, the constituted solution will measure 2 ml.. How many millilitres of the constituted solution must be withdrawn and added to the D5W? If the medication should be infused over half an hour, what is the infusion rate?

(4 marks)

5. IV admixture should be prepared using "Aseptic technique". Define this term.

(2 marks)

6. What are the types of the laminar airflow work bench? Explain the difference between them.

(4 marks)

7. In relation to the preparation of IV admixture, what is the definition of "contamination"? What are the possible sources of contamination?

(4 marks)

End of Section B

Section C (31 marks)

1. Mini Nutrition Assessment questionnaire (MNA) is one of the screening tools used to assess the nutritional status of elderly patients. Mention FOUR elements/questions used in this screening tool.

(4 marks)

2. TPN can be administered through peripheral or central line. Compare between the two routes.

(4 marks)

3. What is the mechanism of each of the following interactions?
   I. Cations can destabilize lipid emulsion used in TPN preparation.

(2 marks)

   II. The interaction between ciprofloxacin and enteral feeding

(2 marks)

4. What are the ideal characteristics of ophthalmic delivery systems?

(4 marks)

5. What are the advantages of inhalation therapy?

(3 marks)

6. In relation to inhalation therapy, explain how particle size distribution plays an important role in determining the drug efficacy and toxicity.

(3 marks)

7. Mention FOUR differences between pMDIs and DPIs?

(4 marks)

8. In SEVEN steps, explain how to use pMDIs.

(5 marks)

End of Section C

Section D (19 marks)

1. What are the plasma data or parameters used to assess drug bioavailability?

(3 marks)

2. What is the difference between “absolute” and “relative” bioavailability?

(2 marks)

3. What are the four types of study design used to establish a bioequivalence?

(4 marks)

4. During the manufacturing of a biological drug, any modifications in certain steps can alter the product’s effectiveness and safety. Mention FOUR of these critical steps.

(4 marks)

5. When a biological drug can be considered as biosimilar?

(3 marks)

6. Mention THREE acceptable differences in a biosimilar drug?

(3 marks)

End of Section D

END of Exam Paper